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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/547,532	08/31/2005	Yasushi Shintani	20039.1USWO	1634
52835 7590 07/17/2009 HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902 MINNEAPOLIS, MN 55402-0902				
EXAMINER				
MACFARLANE, STACEY NEE				
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1649				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/547,532

Applicant(s)

SHINTANI ET AL.

Examiner

STACEY MACFARLANE

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Response to Amendment

1. Claims 1-11 and 13-23 have been cancelled. Claim 12 has been amended and claim 24 newly added as requested in the amendment filed on May 11, 2009. Following the amendment, claims 12 and 24 are pending in the instant application and are under examination in the instant office action.
2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
3. Applicant's arguments filed on May 11, 2009 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. As currently amended, Claims 12 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 12 is vague and indefinite in its recitation of measuring and comparing a signal transduction activity in a cell "capable of producing a protein consisting of ... SEQ ID NO: 8". Firstly, the term "capable of" does not clarify whether it is required that the cells actually express SEQ ID NO: 8 in order for the method to be practiced. Furthermore, without active recited steps, which either lead to the active production of

the protein consisting of SEQ ID NO: 8, or active steps by which one identifies cells that physically express SEQ ID NO: 8, then one of ordinary skill in the art would not be reasonably apprised as to how to ascertain cells that are "capable of", and the metes and bounds the method are unclear.

7. The term "inhibits" in claims 12 and 24 is a relative term which renders the claims indefinite. The term "inhibit" is not defined by either claim, nor does the specification provide a standard for ascertaining the requisite degree. For example, methods comprising contacting cells with toxins that kill the cells and terminates all signal transduction activity, reads upon inhibition in to the extreme. Thus, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

8. Claims 12 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting an essential step, such omission amounting to a gap between the steps. See MPEP § 2172.01. For both claims, the omitted step is the resulting step whereby a substance that exhibits brain/nerve cell protective action is identified.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. As currently amended, Claims 12 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons of record as applied to claim 12 in the Office action mailed February 11, 2009.

As currently amended, Claim 12 is drawn to a method for screening of a substance that exhibits brain/nerve cell protective action, which comprises measuring signal transduction activity of cells capable of expressing SEQ ID NO: 8 in the presence of SEQ ID NO: 2 in the presence or absence of a test compound and identifying a test compound that inhibits the signal transduction activity; newly added Claim 24 is drawn to a method for screening of a substance that exhibits brain/nerve cell protective action, which comprises measuring and comparing binding activity of a protein consisting of SEQ ID NO: 2 and a protein consisting of SEQ ID NO: 8 in the presence or absence of a test compound and identifying a test compound that inhibits the binding activity.

In Remarks filed May 11, 2009, Applicant traverses the rejection on the grounds that the claim amendments recite steps of measuring and comparing signal transduction or binding activity and the methods of measuring where well known in the art at the time of filing. Additionally, Applicant states, "The rejection also seems to question whether substances having neuroprotective activity could be screened. However, example 2 of the specification shows that cerebral infarction is suppressed by suppressing the function of MIP-3 α (See page 104, line 28 - page 105, line 31). This example shows that the present invention is applicable for screening test compounds having a neuroprotective action" (page 5, *Id*). While these arguments have been fully considered they are not found persuasive for the following reasons.

Claim 12 is broadly provides for the screening of a substance that exhibits brain/nerve cell protective action comprising measuring signal transduction activity of any cell in the presence of SEQ ID NO: 2 and a test compound wherein any test

compound that inhibits the signal transduction activity is identified as a neuroprotective substance. Claim 24 is broadly provides for the identification of a neuroprotective substance comprising identifying any test compound that inhibits the binding activity between SEQ ID NO: 2 and SEQ ID NO: 8.

Example 2 of the specification, referenced in Remarks, demonstrates that a specific anti-MIP3 α antibody is neuroprotective in a rat model of cerebral ischemia. However, the claims broadly encompass the identification of any substance that is neuroprotective in the face of any insult or injury comprising merely measuring and comparing signal transduction or binding activity. Neither the instant specification nor the art at the time of filing has provided a nexus between substances that inhibit the binding between SEQ ID NO: 2 and SEQ ID NO: 8 and neuroprotective action. Nor had the instant specification provided a functional correlation between the inhibition of signal transduction of cells in the presence of SEQ ID NO: 2 and neuroprotective cellular mechanisms. Therefore, the instant specification does not demonstrate that the substances identified by the claimed method provide brain/nerve cell protective action with a reasonable expectation of success.

Furthermore, MPEP 2164.08(a) defines a single means claim as a claim which covers every conceivable means for achieving the stated purpose when the specification disclosed at most only those means known to the inventor. This type of claim was held to be nonenabling for the scope of the claim in *In re Hyatt*, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983) because the specification disclosed at most only those means known to the inventor. When claims depend on a recited property (i.e. disruption

of signal transduction activity or and binding activity), a fact situation comparable to Hyatt is possible, where the claim covers every conceivable substance for achieving the stated result while the specification discloses at most only those known to the inventor. This appears to be the instant case and the claims are not commensurate in scope with the specification. Applicant should note that the claims are so broad as to encompass the identification of any test compound that results in cell death, which is the inhibition of the claims taken to the extreme, as a substance that exhibits brain/nerve cell protective action. Or similarly, provides for the identification of detergents or enzyme compounds, which inhibit protein-to-protein interactions, as substances that exhibit brain/nerve cell protective action merely because they inhibit the binding between SEQ ID NOs: 2 and 8. Thus, the method of the claims encompass the identification of an unreasonable array of compounds as having brain/nerve protective action, many of which have no nexus to neuroprotective cellular mechanisms. Therefore, even though the active steps of measuring and comparing can be performed by one of ordinary skill in the art, a skilled artisan would not know how to identify substances as having brain/nerve protective action by performing the method as claimed.

Therefore, Examiner maintains that one of ordinary skill in the art would not know how to practice the method as claimed with a reasonable expectation of success of identifying a substance with brain/nerve cell protective action without making a substantial inventive contribution. Thus, the rejection is maintained.

Conclusion

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M-W and F 5:30 to 2, TELEWORK-Thursdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

/John D. Ulm/
Primary Examiner, Art Unit 1649